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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,211	01/07/2002	Akio Matsuda	1254-0192P	6200

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/042,211	Matsuda et al.
Examiner	**Art Unit**
Michael Borin	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-31* are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examine

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Part III DETAILED ACTION

Claims 1-31 are currently pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1,2,7, drawn to a purified polypeptide encoded by a polynucleotide from an EST library, classified in class 530, subclass 300.

II. Claims 3-6,8,9,11, drawn to isolated nucleic acid, their homologs, expression vectors and cells comprising the vector, classified in class 536, subclass 23.1 and class 935, subclass 66.

III. Claim 10, drawn to cell membrane.

IV. Claim 12, drawn to polynucleotide-based methods of diagnosing a disease, classified in class 435, subclass 6.

V. Claim 13, drawn to polynucleotide-based methods of screening of inhibitors or promoters NF-kB activation compounds , classified in class 435, subclass 6.

VI. Claim 14, drawn to method for producing pharmaceutical composition, classified in class 435, subclass 325.

VII. Claim 15, drawn to kit, classified in class 435, subclass 810.

VIII. Claim 16,17, drawn to an antibody to a polypeptide, classified in class 530, subclass 388.1, and claim 24, drawn to pharmaceutical composition thereof.

IX. Claim 18, drawn to antisense to polynucleotide of Group II, class 536, subclass 23.1, and claim 25, drawn to pharmaceutical composition thereof.

X. Claim 19, drawn to ribozyme.

XI. Claim 20, drawn to method of treatment using compound identified by method of Group V, classified in class 514, in general.

XII Claims 21,22 drawn to pharmaceutical composition produced by method of Group VI, classified in class 514, in general.

XIII. Claim 23, drawn to method of treating inflammation using pharmaceutical composition produced by method of Group VI, classified in class 514, in general.

XIV. Claim 27, drawn to method of obtaining a novel gene.

XV. Claim 28, drawn to computer medium storing sequence of polypeptide or polynucleotide, classified in class 550, subclass 170.

XVI. Claim 29, drawn to method for calculating nucleotide identity, classified in class 702, subclass 19.

XVII. Claim 30, drawn to (unidentified) substrate to polynucleotides of Group II.

XVIII. Claim 31, drawn to (unidentified) substrate to polypeptides of Group I.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II, III, VIII, IX, X, XII are structurally and functionally different products which are made by different methods and have different uses. The examination of the Groups will require different searches of the US Patents and scientific literature and would require consideration of different patentability issues.

Inventions I and II are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group I, the critical feature is a polypeptide whereas for Group II the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group II to be directed as to its synthesis by a polynucleotide, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search

burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions I and VIII are separate and distinct as the polypeptides of Invention I are structurally and biochemically different than the antibodies of Invention VIII. While the antibodies may bind to the polypeptides of Invention I, the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner.

Inventions II and VIII are separate and distinct, as the claims of Invention II are drawn to polynucleotides, while the claim of group VIII is drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention VIII would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

The kit of Group VII is unrelated to product of Group II as it contains a gene, rather than polynucleotides of Group II.

Substrates of groups XVII, VIII have no structural characteristics and are

considered to be structurally unrelated to other claimed products as well as to each other.

Inventions II and IV-VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, methods IV-VI are alternate methods of using the compound of Group II

The methods of groups IV-VI,XI,XIII,XIV,XVI are related as independent methods which differ in the method objectives, with differing steps using differing reagents and materials, to differing ends.

For example, inventions IV and XI are separate and distinct as each method comprises differing steps using differing reagents and materials, to differing ends. Invention IV ends with diagnosing a disease determining presence of a mutation in polynucleotide, while Invention XI ends with the treatment of a disease using a compound of unrelated structure. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the

examiner if not restricted.

Inventions of Groups XVI and I or II are separate and patentably distinct, as a nucleotide or peptide sequence can be recorded on any type of medium other than computer readable (e.g., on paper), and because a computer readable medium can contain any type of information, other than the sequence of polynucleotides or polypeptides of Groups I or II.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on a plurality of independent and/or patentably distinct sequences. Each peptide or nucleic acid sequence is independent and/or patentably distinct because they are unrelated compounds, there is no disclosed core structure required for a common utility, and because each of these compounds possess different structure and/or physico-chemical properties, and/or capable of separate manufacture and/or use. **For an elected Group the Applicants must further elect a single amino acid or nucleic acid sequence.**

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and

are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Examination will be restricted only to a Group drawn to elected sequences.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, and the necessity for non-coextensive literature searches restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one

claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Mr. Michael Woodward, can be reached at (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October 28, 2003

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER